

# GRIFOLS

## Grifols enters into global collaboration and licensing agreement with Selagine to develop immunoglobulin eye drops to treat dry eye disease

- *First-ever ocular surface indication for a Grifols immunoglobulin (Ig) would potentially provide a much-needed treatment for dry eye disease (DED), a condition affecting more than 100 million people globally*
- *Under the terms of the agreement, Grifols to have worldwide exclusive commercial rights to Selagine's treatment upon regulatory authorization, expected in early 2029*
- *A clinical development program will determine the efficacy and tolerability of Grifols Ig eye drops as an anti-inflammatory agent to treat both signs and symptoms of DED*
- *Grifols reinforces its innovation ecosystem through organic development and strategic alliances to accelerate its pipeline and provide breakthrough therapies while driving sustainable business growth and profitability*

**Barcelona, Spain, March 6, 2023** – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines, today announced a global collaboration and licensing agreement with Selagine Inc, a company focused on developing novel therapeutics for ocular diseases, to treat dry eye disease (DED) with immunoglobulin eye drops.

The potential Ig treatment, once it completed clinical development and received regulatory authorizations, would become Grifols' first ocular-surface indicated medicine as well as the company's first-ever product for DED, which affects more than 100 million people globally.

Under their agreement, Grifols will have worldwide exclusive commercial rights to Selagine's treatment, which will be developed combining Grifols' expertise in developing and manufacturing innovative Ig therapies as well as Selagine's cutting-edge research, medical expertise and clinical experience treating debilitating eye diseases. A new product is expected to reach retail pharmacies following regulatory authorization in early 2029.

In a pilot phase I/II clinical trial, Selagine treated subjects with eye drops based on Grifols Flebogamma DIF® twice daily for eight weeks and secured a significant reduction in the signs and symptoms of DED, and with no difference in tolerability or adverse events.

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Several different sources of inflammation, including proteins (cytokines or chemokines), cells (neutrophils, T-cells and dendritic cells) and pathogenic antibodies, are present on the ocular surface in DED and contribute to its signs and symptoms. Selagine's line of research is that the broad-spectrum anti-inflammatory actions of an ocular surface immunoglobulin are superior to currently approved therapies, which are narrow spectrum and limited mainly to targeting T-cell inflammatory mechanism.

According to the agreement, Grifols will fund the entire clinical development program through approval by the U.S. Food and Drug Administration, which will be managed jointly by both companies. This includes the clinical, manufacturing and regulatory activities required for FDA approval for an indication for dry eye disease. Grifols would sub-license the potential treatment and make tiered royalty payments based on net sales as well as milestone payments upon achievement of certain annual sales thresholds.

Grifols continues to innovate and drive long-term strategic business growth through organic initiatives and strategic collaborations such as Selagine.

"Grifols is very excited to combine our synergistic strengths with Selagine in a potentially game-changing treatment for an unmet medical need that can help millions of patients globally with dry eye disease," said Victor Grifols Deu, co-CEO of Grifols. "We are committed to maximizing our deep and ever-growing knowledge of immunoglobulins to treat the broadest range of therapeutic areas."

"Selagine and Grifols have an exceptional opportunity to change the paradigm of dry eye treatment through a novel approach that has the potential to significantly improve the quality of life of patients suffering from this condition," said Dr. Sandeep Jain, MD, founder and President of Selagine and BA Field Professor of Ophthalmology at the University of Illinois Chicago.

## About Dry Eye Disease

It is a common and chronic multifactorial inflammatory disease characterized by insufficient moisture in the outer surface of the eye, leading to dryness, pain, discomfort, diminished quality of life and, in severe cases, permanent vision impairment. Currently approved treatments, such as artificial tears and anti-inflammatories (corticosteroid therapy, cyclosporine therapy and lifitegrast), may take weeks or even months to demonstrate activity.

## About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

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A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 400 across North America, Europe, Africa and the Middle East and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. It provides high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 26,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2022, Grifols' economic impact in its core countries of operation was EUR 9.6 billion. The company also generated 193,000 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information, please visit [www.grifols.com](http://www.grifols.com)

## About Selagine Inc.

Selagine Inc. is a clinical-stage spin-out company from the University of Illinois at Chicago (UIC) that is commercializing technology which was developed within the University of Illinois College of Medicine, Department of Ophthalmology & Visual Sciences. The immunoglobulin eye drops were the result of research & development efforts spanning over a decade with grant funding from the National Eye Institute (NEI)/National Institutes of Health (NIH), Research to Prevent Blindness and UIC's Office of Technology Management.

Selagine is focused on developing novel therapeutics to help patients suffering from a variety of debilitating ocular diseases, and to improve the quality of life in conditions where effective therapies do not exist. Selagine's office is located within the Illinois Medical District and its R&D laboratory is housed in UIC's Technology Innovation Lab, a hub for entrepreneurship and innovation at the University.

For more information, visit [www.selagine.com](http://www.selagine.com)

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predictions of the management team at the time of writing this report, and these are subject to a number of factors that mean that the actual results may be materially different. The future results of the Grifols group could be affected by events relating to its own activities, such as a shortage of supplies of raw materials for the manufacture of its products, the appearance of competitor products on the market, or changes to the regulatory framework of the markets in which it operates, among others. At the date of compiling this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. does not accept any obligation to publicly report, revise or update future projections or assumptions to adapt them to events or circumstances subsequent to the date of writing this report, except where expressly required by the applicable legislation. This document does not constitute an offer or invitation to buy or subscribe shares in accordance with the provisions of the following Spanish legislation: Royal Legislative Decree 4/2015, of 23 October, approving recast text of Securities Market Law; Royal Decree Law 5/2005, of 11 March and/or Royal Decree 1310/2005, of 4 November, and any regulations developing this legislation. In addition, this document does not constitute an offer of purchase, sale or exchange, or a request for an offer of purchase, sale or exchange of securities, or a request for any vote or approval in any other jurisdiction. The information included in this document has not been verified nor reviewed by the external auditors of the Grifols group